

REMARKS

Applicants acknowledge the Examiner's withdrawal of the previously issued restriction requirement. Claims 1-34 are presently pending in the application. Claims 20-27 have been allowed.

Claim 33 has been objected to as allegedly depending from a nonexistent claim 50. As presently amended, claim 33 depends from claim 26. Withdrawal of the objection to claim 33 is therefore warranted.

Claims 1-19 and 28-34 have been rejected under 35 U.S.C. §112, second paragraph, as allegedly incomplete for omitting essential steps. Specifically, the alleged omitted steps are a correlation step between the detected color reaction product and its relationship to the determination of oxidative stress and/or the identification of a mammalian subject in need of medical treatment. By this amendment, claim 1 has been amended to recite: "[a] method of detecting hydrogen peroxides and organic peroxides in a mammalian subject said method comprising: a. obtaining a sample of a biological fluid from the subject; b. mixing the biological fluid with a ferrous reaction reagent comprising 2-deoxyglucose and a ferrous (Fe^{2+}) compound; c. incubating the biological fluid and the reaction reagent; and d. detecting a coloured reaction product."

In addition, in order to more fully define the present invention, Applicants have added claim 35 to the application, which recites: "[t]he method of claim 1 comprising the further step of determining the presence of oxidative stress within the subject, wherein the further step comprises detecting a colorimetric change in the reaction product by comparing the reaction product with a reference standard and correlating the presence of oxidative stress with a difference between the colorimetric properties of the reaction product and the standard."

Withdrawal of the rejection of claims 1-19 under 35 U.S.C. § 112, second paragraph, is respectfully requested.

With respect to the rejection of claims 28-34 as allegedly incomplete for omitting essential steps, it is respectfully submitted that since these claims are product (kit) claims, there can be no omitted step. Withdrawal of the rejection of claims 28-34 under 35 U.S.C. §112, second paragraph, is therefore requested.

Claims 16-19 have been rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite in failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner has required clarification of the term "minimal method." As presently amended, claim 16 no longer recites "minimal method." Withdrawal of the rejection of claims 16-19 under 35 U.S.C. §112, second paragraph, is therefore respectfully requested.

Claims 1, 11, 12, 13, 15-19, 28, 32 and 34 have been rejected under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent No. 5,702,955 to Pugia. Claims 1, 11, 13, 14, 16-19, 28, 29 and 34 have been rejected under 35 U.S.C. §102(b) as allegedly anticipated by Nourooz-Zadeh, et al, (1994) "Measurement of Plasma Hydroperoxide Concentrations by the Ferrous Oxidation-Xylenol Orange Assay in Conjunction with Triphenylphosphine" *Analytical Biochem.* 220:403-409.

As presently amended, step (b) of claim 1 recites "mixing the biological fluid with a ferrous reaction reagent comprising 2-deoxyglucose and a ferrous (Fe^{2+}) compound." Claim 16 has also been amended to recite in relevant part: "determining oxidant level in the biological fluid by mixing the fluid with a reagent comprising 2-deoxyglucose and a ferrous (Fe^{2+})

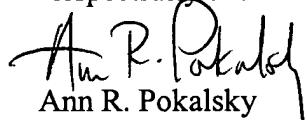
compound." Claim 28 is also amended to recite "a ferrous reaction reagent comprising a solution of 2-deoxyglucose and a ferrous (Fe^{2+}) compound".

Applicants respectfully submit that the ferrous reaction reagent of Pugia comprises 3.1mM metal chelate (including ferrous sulphate), 44 mM malonic acid, 14mM diisopropyl dihydroperoxide and 11.6 mM TMB. Nourooz-Zadeh teaches a ferrous reaction reagent (FOX2 reagent) comprising 250 μ M ammonium ferrous sulfate, 100 μ M xylenol orange, 25 mM H_2SO_4 , and 4mM BHT in 90% (v/v) methanol. Applicant's ferrous reagent comprising 2-deoxyglucose and a ferrous (Fe^{2+}) compound, including when the reagent comprises TBA and EDTA, and when such ferrous ions are supplied by ferrous sulphate, is thus distinguished over both Pugia and Nourooz-Zadeh et al. Withdrawal of the rejection of claims 1, 11, 12, 13, 15-19, 28, 32, and 34 under 35 U.S.C. §102(b) as well as the rejection of claims 1, 11, 13, 14, 16-19, 28, 29 and 34 under 35 U.S.C. §102(b), is therefore respectfully requested.

Claim 29 has been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Pugia. Claim 29 depends from claim 28 and claim 28 is presently amended to recite a ferrous reaction reagent comprising 2-deoxyglucose and a ferrous (Fe^{2+}) compound. Pugia teaches a ferrous reaction reagent comprising 3.1mM metal chelate (including ferrous sulphate), 44 mM malonic acid, 14mM diisopropyl dihydroperoxide and 11.6 mM TMB. Applicant's kit containing a ferrous reaction reagent comprising a solution of 2-deoxyglucose and a ferrous (Fe^{2+}) compound, as well as instructions for carrying out the method of proposed amended claim 1, is neither taught nor suggested in Pugia. Withdrawal of the rejection of claim 29 under 35 U.S.C. § 103(a) is therefore respectfully requested.

In view of the foregoing remarks and amendments, including the submission of new claim 35, it is firmly believed that the present claims are in condition for allowance, which action is earnestly solicited.

Respectfully submitted


Ann R. Pokalsky
Reg. No. 34,697

Dilworth & Barrese LLP
333 Earle Ovington Boulevard
Uniondale, New York 11553
(516) 228-8484
(516) 228-8516
ARP/hh